

**Title: Procedures for allowing Guest/Observer to visit Yenepoya University Ethics
Committee or attend Yenepoya University Ethics Committee meeting**

SOP Code: SOP05/v2

Effective date: 01/08/2016

Prepared by:

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with date
--	---------------------

Reviewed by:

Dr. Ravi Vaswani YUEC SOP Team	Signature with date
-----------------------------------	---------------------

Approved by:

Dr. Sayeegeetha Chairperson, YUEC	Signature with date
--------------------------------------	---------------------

Notified by:

Registrar, Yenepoya University vide Notification No. YU/REG/ACA/YUEC/FERCAP/01/2016 dated 01/08/2016	Signature with date
---	---------------------

Table of Contents:

Sl No	Content	Page No.
1	Purpose	3
2	Scope	3
3	Glossary	3
4	Responsibility	3
5	Detailed Instructions	5
6	Annexures	7
7	Flowchart	7

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Yenepoya University Ethics Committee (YUEC) and the Guest/Observer whenever he/she visits the YUEC Office/Secretariat or attends YUEC meeting. This SOP is needed to ensure adequate protection of confidentiality of information related to research studies

2. Scope:

2.1 This SOP covers the procedures for allowing a guest/observer to visit the YUEC Office/Secretariat and/or observe a meeting in progress.

3. Glossary:

Guest(s)/observer(s) may include a student(s)/trainee(s), member(s) of other ethics committees, surveyor(s), member(s) of regulatory agencies, representative(s) of patient group(s), representative(s) of special interest group(s), representative(s) of accrediting organization(s), representative(s) of Yenepoya University who wish(es) to learn/understand/review/assess the functioning of ethics committees, or to represent participant group(s).

4. Responsibility:

4.1 Member-Secretary:

4.1.1 It is the responsibility of the Member-Secretary in consultation with the Chairperson to decide whether the guest/observer intending to attend the YUEC office/Secretariat or the YUEC meeting, may be allowed.

4.1.2 The Member-Secretary will inform the guest/observer to read, understand, agree and sign the agreement letter prior to visiting the YUEC office or YUEC meeting

4.2 Secretariat:

4.2.1 The YUEC Secretariat after receiving the request letter from the prospective visitor or guest will inform the Member-Secretary

- 4.2.2 The YUEC Secretariat will ensure that the confidentiality letter is duly signed with date by the guest/observer prior to visiting the YUEC office or attending the YUEC meeting.
- 4.2.3 The YUEC Secretariat files this duly signed letter in the respective YUEC file

5 Detailed instructions:

5.1 Decision to allow the visitor/observer:

- 5.1.1 On receiving a verbal or written request from a guest intending to visit the YUEC office or observe the YUEC meeting, the Member-Secretary will inform the Chairperson about the same
- 5.1.2 The request is recorded in the YUEC file stating the reason for the visit
- 5.1.3 The Chairperson and Member-Secretary will decide whether the guest or the observer should be allowed to visit the YUEC Secretariat or attend the YUEC meeting based on the reasons quoted.
- 5.1.4 Once it is decided to allow the guest/observer to visit the YUEC Secretariat or attend the YUEC meeting, the date and time of visit is informed to the guest via an email.

5.2 Signing the Confidentiality agreement from

- 5.2.1 The Secretariat gives the confidentiality agreement form (Ann01/SOP05/v2) to the visitor/observer upon his arrival at the YUEC office on the scheduled date and time
- 5.2.2 The guest/observer will read the form carefully prior to the visit to the YUEC Secretariat or before commencement of the YUEC meeting, whichever is applicable.
- 5.2.3 If there are any doubts, questions, the guest/observer will seek clarifications from the Secretariat/Member-Secretary/member of YUEC.
- 5.2.4 The guest/observer will enter the specified details stating clearly the purpose for the visit, in the given form and sign the confidentiality agreement form in the presence of at least one member of the YUEC, or one administrative staff of the YUEC Secretariat.
- 5.2.5 The Chairperson/Member-Secretary will counter sign the confidentiality agreement form
- 5.2.6 A photocopy of the duly signed and dated document will be provided to the guest/observer

5.2.7 The guest/observer will acknowledge the receipt of the photocopy.

5.3 Filing of the confidentiality agreement forms

5.3.1 The Secretariat will file the original duly signed confidentiality agreement form in the YUEC file for confidentiality agreement forms for visitors of the YUEC

5.3.2 The file is maintained in the secure storage of the YUEC

5.4 Ensuring confidentiality

The guest /observer must implement the clauses of the signed Confidentiality Agreement form.

6 Annexures:

- 6.1 Ann02/SOP05/v2: Request letter to visit YUEC or attend YUEC meeting
- 6.2 Ann01/SOP05/v2: Confidentiality Agreement for Guest/Observer to YUEC
/YUEC Meeting

Ann01/SOP05/v2

Request letter to visit YUEC or attend YUEC meeting

To

The Member-Secretary

Yenepoya University Ethics Centre

Yenepoya University

Sir/Madam,

I request you to permit me to visit the YUEC office/YUEC meeting. The following are my details:

Name:

Designation:

Institution:

Address:

Phone number:

Email address:

Desired date and time of visit:

Purpose of visit:

Thanking you,

Yours sincerely,

Signature with Name and date

Ann02/SOP05/v2

**Confidentiality Agreement Form For Guest / Observer Attendees to YUEC Secretariat/
YUEC Meetings**

Confidentiality agreement

I have read carefully and understood the terms of confidentiality agreement provided by the YUEC Secretariat for visiting the YUEC Secretariat/office on (date) _____ at (time) /attending YUEC meeting on (date) _____ at (time) _____ at (venue)_____

I understand that I am being allowed to visit YUEC office/attend YUEC meeting only as a guest/observer. I may become aware of some confidential information during my visit to YUEC / during the course of the YUEC meeting. I ensure that any confidential information that I come across will be kept confidential through reasonable measures.

I ensure that I will only observe the functioning of the YUEC Secretariat/office and/or meeting without interfering with the discussion in the meeting or disrupting the office material.

I agree to all the terms and conditions.

Signature:

Name

Institution

Date:

Signature of the Chairperson/Member-Secretary

Date:

Acknowledgment:

I, _____ (name) acknowledge that I have received a copy of the agreement signed by the Chairperson YUEC and me.

Signature of guest with date

7 Flowchart

SI No	Activity	Responsibility
1	Receiving request from guest/ observer	YUEC Secretariat/ Member/ Member-Secretary
2	Allowing a guest/ observer	Chairperson
3	Informing guest/ observer about visit/ meeting date and time	YUEC Secretariat
4	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5	Filing of signed confidentiality form in YUEC records	YUEC Secretariat